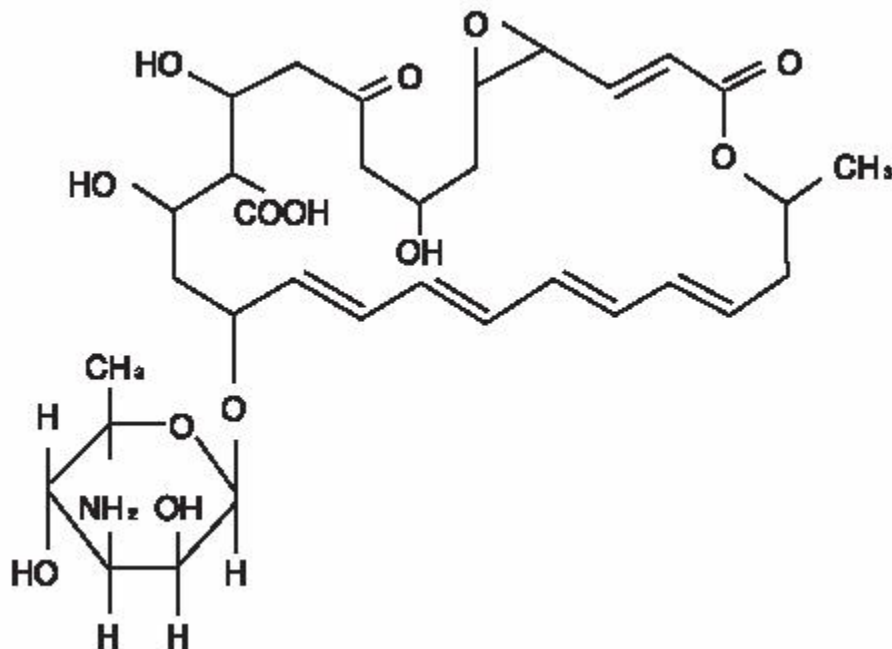


DESCRIPTION

NATACYN® (natamycin ophthalmic suspension) 5% is a sterile, antifungal drug for topical ophthalmic administration. The active ingredient is represented by the chemical structure:

Established name: Natamycin



Chemical name: Stereoisomer of 22-[(3-amino-3,6-dideoxy- β -D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0^{5,7}] octacos-8,14,16,18,20-pentaene-25-carboxylic acid.

Other: Pimaricin

Each mL of the suspension contains: **Active:** Natamycin 5% (50mg). **Preservative:** Benzalkonium Chloride 0.02%. **Inactive:** Sodium Hydroxide and/or Hydrochloric Acid (neutralized to adjust the pH), Purified Water. DM-00

CLINICAL PHARMACOLOGY

Natamycin is a tetraene polyene antibiotic derived from *Streptomyces natalensis*. It possesses *in vitro* activity against a variety of yeast and filamentous fungi, including *Candida*, *Aspergillus*, *Cephalosporium*, *Fusarium* and *Penicillium*. The mechanism of action appears to be through binding of the molecule to the sterol moiety of the fungal cell membrane. The polyenesterol complex alters the permeability of the membrane to produce depletion of essential cellular constituents. Although the activity against fungi is dose-related, natamycin is predominantly fungicidal.* Natamycin is not effective *in vitro* against gram-positive or gram-negative bacteria. Topical administration appears to produce effective concentrations of natamycin within the corneal stroma but not in intraocular fluid. Systemic absorption should not be expected following topical administration of NATACYN (natamycin ophthalmic suspension) 5%. As with other polyene antibiotics, absorption from the gastrointestinal tract is very poor. Studies in rabbits receiving topical natamycin revealed no measurable compound in the aqueous humor or sera, but the sensitivity of the measurement was no greater than 2 mg/mL.

INDICATIONS AND USAGE

NATACYN (natamycin ophthalmic suspension) 5% is indicated for the treatment of fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms including *Fusarium solani* keratitis. As in other forms of suppurative keratitis, initial and sustained therapy of fungal keratitis should be determined by the clinical diagnosis, laboratory diagnosis by smear and culture of corneal scrapings and drug response. Whenever possible the *in vitro* activity of natamycin against the responsible fungus should be determined. The effectiveness of natamycin as a single agent in fungal endophthalmitis has not been established.

CONTRAINDICATIONS

NATACYN (natamycin ophthalmic suspension) 5% is contraindicated in individuals with a history of hypersensitivity to any of its components.

PRECAUTIONS

General

For topical ophthalmic use only — NOT FOR INJECTION. Failure of improvement of keratitis following 7-10 days of administration of the drug suggests that the infection may be caused by a microorganism not susceptible to natamycin.

Continuation of therapy should be based on clinical re-evaluation and additional laboratory studies.

Adherence of the suspension to areas of epithelial ulceration or retention of the suspension in the fornices occurs regularly. There have only been a limited number of cases in which natamycin has been used; therefore, it is possible that adverse reactions of which we have no knowledge at present may occur.

For this reason, patients on this drug should be monitored at least twice weekly. Should suspicion of drug toxicity occur, the drug should be discontinued.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the suspension.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There have been no long term studies done using natamycin in animals to evaluate carcinogenesis, mutagenesis, or impairment of fertility.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with natamycin. It is also not known whether natamycin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. NATACYN[®] (natamycin ophthalmic suspension) 5% should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether these drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when natamycin is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

One case of conjunctival chemosis and hyperemia, thought to be allergic in nature, has been reported.

DOSAGE AND ADMINISTRATION

SHAKE WELL BEFORE USING. The preferred initial dosage in fungal keratitis is one drop of NATACYN (natamycin ophthalmic suspension) 5% instilled in the conjunctival sac at hourly or two-hourly intervals. The frequency of application can usually be reduced to one drop 6 to 8 times daily after the first 3 to 4 days. Therapy should generally be continued for 14 to 21 days or until there is resolution of active fungal keratitis. In many cases, it may be helpful to reduce the dosage gradually at 4 to 7 day intervals to assure that the replicating organism has been eliminated. Less frequent initial dosage (4 to 6 daily applications) may be sufficient in fungal blepharitis and conjunctivitis.

HOW SUPPLIED

15 mL in glass bottles with sterile dropper assembly.

NDC 0065-0645-15

STORAGE: May be stored in refrigerator [(36° - 46° F) (2° - 8°C)] or at room temperature [(46° - 75° F) (8° - 24° C)]. *Do not freeze.* Avoid exposure to light and excessive heat.

Rx Only

*Laupen, J.O.; McLellan, W.L.; El Nakeeb, M.A.: "Antibiotics and Fungal Physiology," Antimicrobial Agents and Chemotherapy, 1965: 1006, 1965.

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